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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,552	07/06/2001	Lauraine Wagter-Lesperance	6580-239	7030

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EXAMINER

SZPERKA, MICHAEL EDWARD

ART UNIT PAPER NUMBER

1644

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/899,552	Applicant(s) WAGTER-LESPERANCE ET AL.	
	Examiner Michael Szperka	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 3 and 5-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21 is/are allowed.
- 6) ☒ Claim(s) 3,5-20 and 22-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

1. Please note that the examiner of record for your application has changed. To aid in paper matching, please address all future correspondence to Michael Szperka, Art Unit 1644, Technology Center 1600.

This application is a continuation-in-part of 09/215,328, now US Patent No. 6,287,564, which claims priority to provisional application 60/068,750.

Applicant's response and amendments received June 13, 2006 are acknowledged.

Claims 1, 2, 4, and 25-52 have been canceled.

Claims 3, 5, 11, 14, 16, 21, 22, 23, and 24 have been amended.

Claims 3 and 5-24 are pending in this application.

Claims 3 and 5-24 are under examination in this office action as they read on methods of ranking the immune response of test animals based on measured antibody responses.

Before setting forth the art rejections, a discussion concerning the effective filing date of the instant claims is warranted. As was stated in the office action mailed March 13, 2006,

It is noted that for claims 4, 5 and 22-24, the effective filing date is limited to the disclosure of the instant application. So, for prior art purposes the date of invention for claims 4, 5 and 22-24 is 7-6-01.

Dependent claims 4, 5, and 22-24 recited weighting coefficients for use in the recited methods that were not supported by the priority documents. Applicant's claim amendments received June 13, 2006 have canceled claim 4, changed the dependency of claim 5, and changed the wording of claims 22-24. Claims 22-24 previously recited "weighted with a coefficient greater than 1" while claim 4 recited "multiplied with a coefficient greater than 1." These claims now recite "given greater weight than the

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primary response". US patent 6,287,564 discloses in lines 13-50 of column 11 a method of ranking immune responses in animals undergoing periparturition by measuring primary, secondary, tertiary, and quaternary antibody responses, wherein animals exhibiting negative secondary or tertiary responses are weighted with a positive coefficient of about 1.5. Giving a particular response greater weight is a broader concept than weighting with a coefficient of about 1.5 since the weighting coefficient is not specified. Further, while weighting with a coefficient of 1.5 is disclosed as part of a specific method, this coefficient does not appear to be disclosed for use in broader methods of ranking immune responses for any stressor that do not require primary, secondary, tertiary, and quaternary measurements. Therefore, based upon applicant's claim amendments, the effective filing date for claims 3, 5-20, and 22-24 is July 6, 2001, the filing date of the instant application.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The rejection of claims 1-3 and 6-20 under 35 U.S.C. 102(b) as being anticipated by Wagter et al. (J. Dairy Science, 1996, Vol. 79(Suppl 1), page 119, reference 25 in the IDS submitted 11-5-01) has been withdrawn.

Specifically, applicant's claim amendments received June 13, 2006 have introduced limitations concerning weighting coefficients that are not disclosed by Wagter et al. However, it is noted that applicant has not provided additional information concerning the content disclosed on the poster presented by Wagter et al. at the 91<sup>st</sup> Annual meeting of the American Dairy Science Association, held July 14-17 in Corvallis, Oregon. Applicant is again requested to furnish this material so that the record is clear that weighting coefficients were not used as part of the immune response ranking

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method disclosed by Wagter et al. Further failure to reply to the actual disclosure of the entirety of poster presentation disclosure will result in a 37 CFR 1.105 request.

4. Claims 3 and 5-24 as amended June 13, 2006 are rejected under 35 U.S.C. 102(b) as being anticipated by CA 2,255,423, publication date of 6-10-00 for the reasons of record.

The office action mailed June 30,2005 states that:

The '423 patent application teaches ranking an immune response of a test animal by immunizing the animals with at least one antigen at least once before the onset of stress and at least once during the stress measuring the antibody response of the animals to the at least one antigen at least once before the stress and at least twice during the stress and providing a total antibody response by adding the antibody responses for each measurement and wherein when the test animal total antibody response is higher than the average, classifying the animal as a high immune responder. In addition the reference teaches multiplying the negative changes in antibody changes during the stress with a co-efficient of about 1.5 (see page 19-20 in particular).

The claimed invention is anticipated by the prior art.

And the office action mailed March 13, 2006 states that:

It is noted claims 22-24 are included in this rejection as CA 2,255,423, also teaches determining secondary, tertiary and quaternary responses and weighing negative responses appropriately with a coefficient of about 1.5, (see pages 19-20 in particular).

Applicant's arguments filed 11-30-05 have been fully considered but are not found persuasive.

Applicant argues the disclosure of the CA 2,255,423 document and the priority document 09/215,328 are equivalent and so a rejection under 35 USC 102 is untenable.

The claims are drawn to a coefficient of greater than 1, which only find support in the instant specification. The date for the claims 4-5 and 22-24 is 7-6-01

The CA 2,255,423 document discloses the claim limitation of "coefficient of about 1.5", meeting the limitation of greater than 1. The prior art rejection is maintained.

Applicant's arguments filed June 13, 2006 have been fully considered but they are not persuasive. Applicant argues that the limitations of claim 4 have been incorporated into independent claim 3 and that the phrase "given greater weight than changes in antibody response at other times" is supported by the priority documents. As such, applicant argues that the instant claims are entitled to the benefit of the filing date of the priority applications and therefore the '423 patent is not prior art.

This argument is not convincing because the concept of giving greater weight than changes at other times is broader than that disclosed in the priority documents. Specifically, the priority documents disclose specific numbers for the weighting coefficient used in determining antibody responses at specific measurement times. Such a disclosure does not support the more generic concept of giving greater weight to changes during stress as compared to other, non-recited times. As such, the species disclosed in the priority documents do not support the instant claimed genus. It should be noted that the disclosure of the '423 patent is identical to that of priority application 09/215,328. The instant claims do not enjoy the benefit of the filing date of the priority documents for the reasons discussed above, and as such the more narrow teachings of the '423 patent anticipate the broader instant claimed method.

Applicant also argues that claim 5 is not anticipated because the priority documents disclose the specific weighting coefficient of 1.5.

This argument is not convincing because the priority documents disclose a weighting coefficient of 1.5 as part of a method of ranking immune responses that comprises additional method steps and is limited to the stress of periparturition. The method recited in instant claim 5 is broader than the disclosure of the priority document because claim 5 does not comprise all of the limitations disclosed by the priority document, and as such the method of claim 5 as currently recited is not supported by the priority document.

The rejection of record is maintained.

5. The following is a new ground of rejection necessitated by applicant's amendment to the claims received June 13, 2006.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 3, 6-20 and 22-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant has amended independent claims 3, 22, 23 and 24 on June 13, 2006 to recite the limitation that negative changes in antibody responses are "given greater weight" than changes in antibody responses at other times. Claims 22-24 previously recited that such changes were "weighted with a coefficient greater than 1" while claim 3 did not recite any weighting values or coefficients.

Applicant has argued on page 9 of the response that the amendments to introduce the limitation of "giving greater weight" do not constitute new matter based upon the disclosure found from line 27 of page 43 to line 7 of page 44 of the instant specification. Applicant further states in the reply that "Accordingly it would be clear to a person skilled in the art that the Applicants intended that changes in antibody response during this time period (i.e. during the stress) should be given more weight in a method of ranking an immune response."

This argument is not convincing that the new limitation of "giving greater weight", a limitation broader in scope than weighting with a coefficient greater than 1, is not new matter. Specifically, the specification and claims as filed indicate "a coefficient greater than 1". While a coefficient greater than 1 would "give greater weight", the concept of giving greater weight is not limited to multiplication with a number greater than 1. This is because a specific value could be added to negative changes in antibody responses rather than multiplying by a coefficient greater than 1, or non-negative changes could be multiplied by a fractional value such as 0.5 to give greater weight to negative changes in antibody responses. As such the recitation of "given greater weight" in the independent claims as amended broadens the scope of claimed subject material beyond that which was disclosed in the application as filed. Therefore, applicant's claim amendments received June 13, 2006 have introduced new matter into the claims.

***Claim Objections***

8. Claim 11 is objected to because the claim should recite (SEQ ID NO:1) rather than [SEQ ID NO::1] since it is customary to use a single colon and parentheses rather than brackets.

9. Claim 21 is allowable.

10. Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 8:00-4:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Szperka, Ph.D.  
Patent Examiner  
Technology Center 1600  
August 9, 2006

  
8/19/06  
**G.R. EWOLDT, PH.D.**  
**PRIMARY EXAMINER**